

Special toothpaste may lower risk of allergic reactions for adults with peanut allergy

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Oral immunotherapy for peanut allergy—introducing small amounts of peanut over a period of time to cause less of a reaction if the person eats something with peanut—has been used by allergists for years to help

desensitize those with peanut allergy.

A late breaking abstract, "A Randomized, Placebo-Controlled Phase 1 Safety Study of OMIT in Adults with Peanut Allergy," being presented at the American College of Allergy, Asthma and Immunology (ACAAI) [Annual Scientific Meeting](#) in Anaheim, Calif. demonstrates that a specially formulated toothpaste can be successfully used for oral mucosal immunotherapy (OMIT).

"OMIT uses a specially formulated toothpaste to deliver allergenic [peanut](#) proteins to areas of the oral cavity," says allergist William Berger, MD, ACAAI member and author of the study. "OMIT as a delivery mechanism for peanut protein has great potential for food [allergy](#) desensitization. Due to its targeted delivery and simple administration, it supports the goal of improved adherence."

This study enrolled 32 adults, age 18–55, with [peanut allergy](#) in a 3:1 ratio to receive either an escalating dose of INT301 or placebo. Inclusion criteria included a positive SPT with a wheal diameter at least 3mm greater than control and/or psIgE ≥ 0.35 kU/L. Additionally, subjects were required to fail an oral food challenge ≤ 100 mg of peanut protein.

During this 48-week trial, safety was monitored during the up-dosing and maintenance phases. Exploratory biomarkers were also evaluated, and oral food challenges were conducted. (Exploratory biomarkers are blood tests used to show if a person's immune system is responding to treatment with an allergen such as peanut.)

"We noted that 100% of those being treated with the toothpaste consistently tolerated the pre-specified protocol highest dose," says Dr. Berger. "No moderate nor severe systemic reactions occurred in [active participants](#). Non-systemic adverse reactions were mostly local (oral itching), mild, and transient. There was 97% adherence to treatment with

no dropouts due to study medication. OMIT appears to be a safe and convenient option for adults with food allergies. The results support continued development of this toothpaste in the pediatric population."

In this phase 1 OMEGA trial, adherence and safety profile of INT301 successfully achieved the primary and secondary endpoints. Immunologic response to treatment suggests further evaluation. These results support continued development of INT301 in the pediatric population.

Additional [long-term studies](#) are planned to further evaluate the ongoing use of the [toothpaste](#) therapy to provide long-term protection against accidental ingestion of peanut.

Provided by American College of Allergy, Asthma, and Immunology

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